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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,411	08/03/2000	Xu Cao	D6258	9593

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09/11/2002

Benjamin Aaron Adler
McGregor & Adler LLP
8011 Candle Lane
Houston, TX 77071

EXAMINER

LACOURCIERE, KAREN A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/11/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,411

Applicant(s)

CAO ET AL.

Examiner

Janet L. Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

As discussed in an interview with Applicant's representative, Colleen Werner, and Examiner Jane Zara on June 17, 2002, the Notice to Comply with Requirements for patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures mailed 06-05-02, is withdrawn because the application does not disclose any nucleotide or amino acid sequences.

Election/Restrictions

Applicant points out that claims 13 and 14 were not included in the restriction requirement set forth in the prior Office action, mailed 12-26-01, and appear to be properly grouped with the invention of Group VI, which is appropriate. Therefore, Applicant correctly sets Group VI forth as claims 11-14.

Applicant's election with traverse of Group VI, claims 11-14, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the search of Group V and VI is coextensive, have the same classification and perform the same function. This is not found persuasive because the search of Group V and VI would not be co-extensive. The methods of Group VI and V are unrelated in that the steps of each method are different. For example, in the methods of Group VI the method steps involve determining binding to DNA, whereas the methods of Group V determine the transcription of a gene. The differences in detection result in methods that are performed using different reagents and different steps and, therefore, would result in a different search for each Group. Although DNA binding may be involved in the transcriptional repression of Group VI, the methods of determining claimed would

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encompass method steps which are different than determining binding, as performed in the methods of Group V, and the search would not require the search of Group V.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 11-14 are drawn to methods of screening for a compound that disrupts transcriptional repression of a gene wherein a Smad6/Hoxc-8 protein complex is formed. The specification as filed does not provide any structural information, ie. sequence, for Smad6 or Hoxc-8 such that the skilled artisan would recognize the

common structural features of proteins encompassed in the terms Smad6 and Hoxc-8. It is noted that the specification incorporates by reference publications that include sequences for Smad6 and Hoxc-8 (see page 31 of the specification), however, incorporation by reference of "essential material", ie. the structural information required to describe the claimed invention in this case, may not be incorporated by reference to non-patent publications. (see MPEP 608.01(p)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-14 are indefinite due to the recitation "Smad6" and "Hoxc-8". It is unclear what proteins would be encompassed in the terms "Smad6" and "Hoxc-8", because the specification has not provided a definition for what proteins would be encompassed in these terms, or enough information on the structure of these proteins, such that the skilled artisan would know what proteins are encompassed in these terms. For example, the prior art recognized some proteins that would be encompassed by the terms "Smad6" and "Hoxc-8", because these names are used in the prior art, however, it is unclear what other proteins would be encompassed in these terms because the names assigned to proteins are not necessarily used consistently in the art. For example, what proteins would be encompassed by these terms, but referred to in the

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prior art by an alternative name? The specification has not provided enough structural information or characteristics of "Smad6" and "Hoxc-8" proteins such that the skilled artisan could determine what proteins are encompassed in the claims, but referred to using an alternative name.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
September 9, 2002


PATENT EXAMINER